UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

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UNITED STATES OF AMERICA *ex rel.* MICHAEL DAUGHERTY BRINGING THIS ACTION ON BEHALF OF THE UNITED STATES OF AMERICA, THE STATE OF TEXAS, THE STATE OF GEORGIA, THE COMMONWEALTH OF VIRGINIA, THE STATE OF TENNESSEE, THE STATE OF NEW YORK, THE STATE OF FLORIDA, THE DISTRICT OF COLUMBIA, AND THE STATE OF INDIANA *Plaintiff and Relator,* v. BOSTWICK LABORATORIES c/o Dennis M. Ryan 707 E Main Street, 11th Floor Richmond, Virgina 23219 *Defendant.*	:	Civil Action No. 1:08CV354 SPIEGEL, J. Qui Tam Action **FILED UNDER SEAL** Pursuant to 31 U.S.C. 3720(b)(2) and S.D. Ohio Civ. R. 3.2

COMPLAINT FOR VIOLATIONS OF THE FALSE CLAIMS ACT

Relator Michael Daugherty, acting on behalf of the United States of America, the State of Texas, the State of Georgia, the Commonwealth of Virginia, the State of Tennessee, the State of New York, the State of Florida, the District of Columbia, the State of Indiana, and himself, alleges as follows:

INTRODUCTION

1. Plaintiff-Relator Michael F. Daugherty brings this action on his own behalf and on behalf of the United States of America to recover damages and penalties under the False Claims Act, 31 U.S.C. §§ 3729-3733 (False Claims Act), against Defendant Bostwick Laboratories for the submission of false claims to Medicare, Medicaid, and other federally-funded healthcare programs for non-allowable laboratory services conducted without physician's order as part of an improper "reflex testing" scheme and for billing federally-funded healthcare programs for laboratory services unlawfully referred to Bostwick.

2. Specifically, Bostwick Laboratories is engaged in an ongoing scheme to conduct expensive Fluorescent In Situ Hybridization (FISH) testing on urine specimens with positive or atypical urology results without the treating physician's knowledge, consent, or order. Secondary testing based on the outcome of an initial test is generally called "reflex testing" and is not covered or payable by federally-funded health programs unless it is ordered by the treating physician.

3. Laboratory claims for tests performed without regard to the medical appropriateness of the test to the beneficiary's treatment plan are not allowable under Medicare or Medicaid. Defendant's illegal policy to automatically perform reflex tests on patients without a treating physician's knowledge or consent resulted in the submission of false claims to Medicare and other federally-funded health care programs.

4. Bostwick also engages in an illegal patient-referral scheme whereby Bostwick agrees to provide referring physicians with illegal incentives in exchange for referrals for Bostwick's laboratory services, including FISH tests, from those physicians.

Such quid pro quo arrangements constitute unlawful financial relationships under the Stark laws and the Anti-Kickback Act, thus rendering any submissions for reimbursements for services performed on such referred specimens false claims

JURISDICTION AND VENUE

5. This action arises under the False Claims Act, 31 U.S.C. §§ 3729-3733.

6. Subject-matter jurisdiction lies under 31 U.S.C. § 3732 (a) and 28 U.S.C. § 1331, and personal jurisdiction lies because defendant does business in the Southern District of Ohio.

7. Venue is proper in this District Ohio under 28 U.S.C. 1391(b) and (c) and 31 U.S.C. 3732(a) because defendant employs personnel and transacts substantial business in the Southern District of Ohio and thus many of the facts that form the basis of this Complaint occurred within said district.

8. The facts and circumstances alleged in this complaint have not been publicly disclosed in a criminal, civil or administrative hearing, nor in any congressional, administrative, or government accounting office report, hearing, audit investigation, or in the news media.

9. Relator is an "original source" of the information upon which this complaint is based, as that term is used in the False Claims Act.

10. Relator provided disclosure of the allegations of this complaint to the United States prior to filing.

PARTIES

11. The real party in interest to the claims of this action is the United States of America.

12. Relator Michael Daugherty is a resident of Georgia and a citizen of the United States. He is the President of LabMD, an Atlanta-based urology and uropathology laboratory specializing in addressing the needs of urologists.

13. Defendant Bostwick Laboratories, Inc. (hereinafter also referred to as "Bostwick") is a Virginia corporation, which operates laboratories in Virginia, Florida, Arizona, New York, and London, England for the provision of laboratory and pathology services to physicians, patients, and managed care organizations. These laboratories accept specimens from various regions of the United States, including from Ohio. These services include cytology interpretation services ordered by physicians.

RULE 9(b), FED. R. CIV. P. ALLEGATIONS

14. Much of the documentary evidence necessary to prove the allegations in this Complaint is in the exclusive possession of either the defendant or the United States.

15. In the course of his business, Relator provides similar laboratory services to physician customers, some of which have been or currently are also customers of Bostwick Laboratories.

16. Relator is also familiar with Bostwick's internal structure, policies, and procedures due to a prior business relationship between Bostwick and LabMD's predecessor, Southern Diagnostics, from 2001 to 2003 in which Bostwick performed

diagnostic testing on samples submitted to Southern Diagnostics. As a result of this contractual business relationship, Relator worked closely with Bostwick personnel.

17. With respect to each allegation herein made upon information and belief, Relator has, based upon his knowledge, data, and experience, a reasoned factual basis to make the allegation but lacks complete details of it.

18. Relator became aware of the conduct alleged herein after he was contacted by Bostwick customers who personally observed and provided information to Relator regarding the illegal billing of Bostwick, including information regarding the corporate practices for the unauthorized testing performed as well as representative claims information. Relator also became aware of the conduct alleged herein after he was advised by sales representatives that Bostwick Laboratories is engaging in illegal schemes to incentivize increased referrals of business and was provided with documentation of Bostwick's solicitations of such illegal referral arrangements.

19. However, Relator does not have access to all of the information regarding the claims for payment submitted or caused to be submitted by Bostwick. This information is in Bostwick's exclusive possession and control. Indeed, Bostwick refused to provide such information in response to the request of its customer.

20. Bostwick has submitted and caused to be submitted and, upon information and belief, continues to submit or cause to be submitted to the United States false claims for payment for noncovered and nonpayable laboratory testing which were performed and billed without order of the patient's physician, or performed as a result of an illegal compensation arrangement in violation of the Stark and Anti-kickback laws.

21. Upon information and belief, Relator alleges that Bostwick's inflated billing scheme has occurred continuously since the 2005 addition of Medicare reimbursement for Fluorescent In Situ Hybridization (FISH) testing of cytology specimens.

FACTUAL ALLEGATIONS

I. FISH Testing and Requirements Applicable to Bostwick Labs.

A. Urine Cytology and Fluorescence In Situ Hybridization (FISH) Testing for Bladder Cancer.

22. Urine cytology is a routine test ordered by urologists as a method to detect cancer and inflammatory diseases of the urinary system, including the bladder, urethra, uterus, and kidneys. In a urine cytology test, a urine sample is sent to a laboratory and examined under a microscope for cancerous or precancerous cells.

23. The 2001 AUA Best Practices Policy on Asymptomatic Microscopic Hematuria [blood in the urine] recommends that all patients with blood in the urine should undergo cytology or cystoscopy, depending on the patient's risk factors.[1] *See generally* Gary D. Grossfeld, *et al.*, *Asymptomatic Microscopic Hematuria in Adults: Summary of the AUA Best Practice Policy Recommendations*, 63 Am. Family Physician 1145 (March 15, 2001), *available at* http://www.aafp.org/afp/20010315/1145.html (last visited Apr. 10, 2008)

24. Urologists have typically relied on urine cytology (microscopic examination of urine cells), cystoscopy (bladder and urethra examined using a thin, lighted

[1] "While hematuria is the most common presenting sign of bladder cancer, most patients with hematuria do not have bladder cancer." National Cancer Institute, http://www.cancer.gov/cancertopics/pdq/screening/bladder/HealthProfessional/page3

instrument called a cystoscope), and biopsy to conduct additional evaluation for the diagnosis of bladder cancer.

25. The United States Food and Drug Administration ("FDA") has approved certain other noninvasive, urine-based marker tests as adjunctive (secondary) tests to aid in the diagnosis and surveillance of patients with bladder cancers.

26. In January 2005, the FDA gave pre-market approval to UroVysion's Fluorescent In Situ Hybridization (FISH) test for bladder cancer "in conjunction with and not in lieu of current standard diagnostic procedures, as an aid for the diagnosis of initial bladder carcinoma in patients with hematuria [blood in the urine] and subsequent reoccurrence in patients previously diagnosed with bladder cancer." Letter from Robert L. Becker, Director, Division of Immunology and Hematology, FDA, to Larry W. Clark, Manager of Clinical Affairs, Vysis, Inc. (Jan. 24, 2005), *available at* http://www.fda.gov/cdrh/pdf3/P030052a.pdf.

27. FISH testing uses small, fluorescent-labeled DNA molecules (probes) to identify specific areas of DNA in the cells of a urine specimen under a microscope in order to determine if abnormal cells and/or chromosomal aberrations are present. The probes can be applied manually or with an automated system. Specifically, the test requires the following steps:

- A sample of urine is taken from the patient.
- The cells in the urine are spun down.
- The cell pellet is spread on a microscope slide and dried.
- The cells on the slide are treated to separate the two strands of the DNA.
- Fluorescent DNA probes are added to the sample and incubated.
- The sample is analyzed by a pathologist or medical technologist using a microscope equipped to detect fluorescence.

- The fluorescence patterns seen in the cells on the slide are used to determine whether [abnormal cells] are present.

FDA, New Device Approval—UroVysion Bladder Cancer, http://www.fda.gov/cdrh/mda/docs/p030052.html.

28. Prior to 2005, FISH testing was only approved for tissue specimens, and Medicare and Medicaid paid only for FISH tests performed on tissue specimens. Beginning in 2005, FISH testing was approved for both tissue and cytology specimens. At that time, Medicare's and Medicaid's reimbursement coding system was revised to allow payment for FISH testing of both tissue and cytology specimens (*see infra* paragraphs 37-38).

29. As an adjunctive test only, FISH does not replace urine cytology and is an added cost.

30. There is dispute among urologists regarding the effectiveness of FISH testing for diagnostic evaluation. The American Urological Association ("AUA") does not yet include FISH or other urine-marker testing as part of its Best Practices Policy Recommendations for the diagnostic evaluation of bladder cancer, and instead states that "insufficient data are available to recommend their routine use in the evaluation of patients with microscopic hematuria." *Asymptomatic Microscopic Hematuria in Adults: Summary of AUA Best Practice Policy Recommendations*, 63 Am. Fam. Physician 1145, 1151 (March 15, 2001), *available at* http://www.aafp.org/afp/20010315/1145.html.

31. Rather, the AUA recommends that if malignant or atypical/suspicious cells are identified in urine cytology, "cystoscopy is required because the presence of hematuria is a significant risk factor for malignancy in such patients." *Id.* at 1150.

B. Submission of FISH testing claims for payment under federally-funded healthcare programs.

32. Laboratory services, including the FISH test, are paid for under Part B of the Medicare program and by state Medicaid agencies. Such services are also covered under other federally-funded healthcare programs.

33. The Medicare program was created in 1965 as part of the Social Security Act (SSA), 42 U.S.C. § 1395 *et seq*. Under the authority of that Act, the Secretary of HHS administers the Medicare Program through Centers of Medicare and Medicaid Services (CMS). The Secretary also promulgates rules and regulations governing the payment of claims, 42 C.F.R. § Parts 400-end.

34. The Medicare program consists of two parts. Medicare Part A authorizes the payment of federal funds for hospitalization and post-hospitalization care. 42 U.S.C. § 1395c-1395i-2 (1992). Medicare Part B authorizes the payment of federal funds for medical and other health services, including without limitation physician services, supplies and services incident to physician services, laboratory services, outpatient therapy, diagnostic services, and radiology services. 42 U.S.C. § 1395(k), 1395(i), 1395(s).

35. The Medicaid program was also created in 1965 as part of the Social Security Act, which authorized federal grants to States for medical assistance to low-income persons, blind, disabled, or members of families with dependent children or qualified pregnant women or children. The Medicaid program is jointly financed by the Federal and State governments. The Health Care Financing Administration (HCFA) administers Medicaid on the federal level. Within broad Federal rules, each State

decides eligible groups, types and range of services, payment levels for services, and administrative and operating procedures. The states directly pay providers, with the states obtaining the federal share of the payment from accounts which draw on funds belonging to the United States Treasury. 42 C.F.R. §§ 430.0-430.30 (1994). The Federal share of each state's Medicaid program varies.Various other federally-funded medical coverage programs exist to help their enrollees cover the costs associated with medical care, including the Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS"), TRICARE, and the Veterans Administration, among others.

36. Medicare contracts with private companies to process claims for Medicare payment. Part A reimbursement is processed through fiscal intermediaries. Part B reimbursement is processed through Medicare carriers. The carriers applicable to Defendant's laboratory sites are:

Richmond, VA	Trailblazer Health Enterprises, LLC
Uniondale, NY	Empire Medicare Services
Orlando, FL	First Coast Service Options, Inc.
Tempe, AZ	Noridian Administrative Services, LLC
Nashville, TN	CIGNA Government Services

37. Claims for Part B laboratory services are submitted using Current Procedural Terminology (CPT). CPT is a listing of descriptive terms and identifying codes for reporting medical services and procedures which was first developed by the American Medical Association, and adopted by CMS as part of its Healthcare Common Procedure Coding System (HCPCS) for reimbursement of claims. The use of HCPCS is currently required for the reimbursement of federally-funded healthcare claims.

38. Prior to 2005, there was no allowable reimbursement for FISH testing of urine specimens. Rather, there was only a CPT code for FISH testing of tissue performed by the laboratory physician, 88365. In 2005, CPT was revised to delete the limitation for tissue, and now allows reimbursement for FISH testing for both tissue and cytology specimens. Two additional CPT codes were also added to differentiate FISH testing performed quantitatively using both computer-assisted and manual methods (88367 and 88368, respectively), while reserving 88365 for qualitative analysis.

39. The CPT codes applicable to FISH testing for bladder cancer are:

88365	In situ hybridization performed by a physician, one probe (used prior to January 1, 2005)
88367	In situ hybridization performed by a physician using computer-assisted technology, one probe (used post January 1, 2005)
88368	In situ hybridization performed by a physician, manual (used post January 1, 2005)
88271-88275	In situ hybridization performed by a non-physician

40. FISH tests are considered expensive add-on tests. The reimbursement for cytology, for example, may range from $59 - $73. The reimbursement for a FISH test ranges from $556 to $909 (FISH tests are coded in units for each fluorescent probe used; and four probes are generally used. For example, the CPT codes 88365, 88367, and 88368 for each probe may range from $139/unit to $227/unit. The total reimbursement would be that amount times the number of units or probes.)

41. FISH tests are generally performed by physicians, and, when used to detect bladder cancer, require four units.

1. Test Must be Furnished under Specific Order of Treating Physician.

42. Section 1862(a)(1)(a) of the Social Security Act provides that Medicare payment will only be made for services that are reasonable and necessary. The Code of Federal Regulations provides that all diagnostic tests "must be ordered by the physician who is treating the beneficiary, that is the physician who furnished the consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem." 42 C.F.R. § 410.32 (a). "Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary." *Id*. These prohibitions apply to claims submitted to other federally-funded healthcare programs.

43. Independent diagnostic testing facilities (IDTF) may only perform procedures specifically ordered in writing by the physician that is treating the beneficiary. 42 C.F.R. § 410.33 (d). "The IDTF may not add any procedures based on internal protocols without a written order from the treating physician." *Id*.

44. Similarly, federal Medicaid regulations also specify that federal financial participation is only provided for laboratory services which are ordered by the physician. *See* 42 C.F.R. § 440.2 (defining federal financial participation);§ 440.20 (defining outpatient hospital services); § 440.30 (defining other laboratory and x-rays services). Medicaid regulations in the States of Ohio, Florida, Georgia, Indiana, New York, Virginia, Tennessee, as well as the District of Columbia also specifically adopt the mandate that covered laboratory services only include those provided upon a physician's order. *See, e.g.,* D.C. Department of Health, Provider Billing Manual: Independent Laboratories and X-Rays §§ 10, 13.3 (2002); Ohio Admin. Code § 5101:3-

11-07(A)(2) (2006); Fla. Admin. Code Ann. r 59G-4.190 (implementing Handbook 2-6); Ga. Department of Community Health, Policies and Procedures for Independent Lab Services Program § 601.7; 405 Ind. Admin. Code 5-18-3(a) (2007); N.Y. Comp. Codes R. & Regs. tit. 18, § 505.7(c)(1) (2002); Va. Department of Medical Assistance Services, Independent Laboratory Manual, Ch. IV, 1 (1999); Tenn. Comp. R. & Regs. 1200-13-16-.05 (2007).

45. As further explained in the Medicare Carrier's Manual:

> The treating physician/practitioner must order all diagnostic tests. For a test to be reasonable and necessary, it must be both ordered by the physician and the ordering physician must use the result in the management of the beneficiary's specific medical problem.... A testing facility that furnishes a diagnostic test ordered by the treating physician/practitioner may not change the diagnostic test or perform any additional diagnostic test without a new order.

M.C.M., Chapter 15 § 80.6.2 (Transmittal 79); *see also* § 15021.B.

46. There are only three exceptions to the testing facility's mandate to obtain a new order for any additional diagnostic tests. First, if the testing facility could not reach the treating physician/practitioner to change the order or obtain a new order and documents this in the medical record, the additional diagnostic test could be furnished if all of the following criteria applied:

- the facility performed the test ordered;
- medical necessity is documented by the interpreting physician based on an abnormal result;
- delaying the performance of the additional test would have an adverse effect on the care of the beneficiary;
- the result of the test is communicated to and used by the treating physician/practitioner in the treatment of the beneficiary; and
- the interpreting physician documents in his/her report why the additional testing was done.

M.C.M. Chapter 15 § 80.6.4 (Transmittal 79); *see also* § 15021.D.

47. Second, if the beneficiary is not a hospital inpatient or outpatient, an interpreting physician at a testing facility (1) may determine the parameters of the diagnostic test itself, if not specified in the order; (2) may modify an order with clear and obvious errors that would be apparent to a reasonable layperson; or (3) may cancel an order because the beneficiary's physical condition prevented performance. M.C.M. Chapter 15 § 80.6.5 (Transmittal 79); *see also* § 15021.E.

48. Third, there is also a surgical/cytopathology exception for pathology specimens that do not specify all the medically necessary tests to evaluate and report to the practitioner; in that case (not applicable here), the pathologist may perform additional tests if they are medically necessary to the complete and accurate diagnosis, the results are communicated to and used by the treating practitioner and the pathologists documents why the additional testing was done. M.C.M. Chapter 15 § 80.6.6 (Transmittal 79); *see also* § 15021.F.

49. The FISH reflex testing by Bostwick alleged herein does not meet any of these exceptions.

2. Reflex Testing is Not Allowable under the Medicare Program without Physician's Order.

50. Reflex testing occurs when a second test is performed by a laboratory based on the result obtained on an ordered test.

51. Reflex tests performed without the physician's order are not reasonable and necessary under Medicare or other federally-funded healthcare programs. Only reflex testing performed pursuant to the express consent of the physician may be acceptable if the second, reflexed test is medically appropriate.

52. The Office of Inspector General (OIG) issued Compliance Program Guidance for Clinical Laboratories in August 1998, which specified: "Laboratories cannot alter the physician's order in any way either increasing or decreasing the number of services performed without the express consent of the ordering physician or other authorized individual." 63 Fed. Reg. 45076, 45080 (August 24, 1998).

53. The OIG Guidance further stated: "only tests that are ordered by an authorized individual or physician, are performed and meet Medicare's conditions of coverage are reimbursable by Medicare." *Id.* at 45080-81.

54. As to reflex testing, the OIG Guidance stated:

> Reflex testing occurs when initial test results are positive or outside normal parameters and indicate that a second related test is medically appropriate. In order to avoid performing unnecessary reflex tests, labs may want to design their requisition forms in such a way which would only allow for a reflex test when necessary. Therefore, the condition under which the reflex test will be performed should be clearly indicated on the requisition form.

Id. at 45081.

55. The National Correct Coding Initiative (NCCI) Policy Manual for Medicare Services also addresses reflex testing. That Manual, which accompanies the Current Procedural Terminology maintained by the AMA and adopted by CMS, makes clear that it is not appropriate to report a CPT code for additional follow-up testing unless it is implicit in the physician's order (in the case, for example, that the additional test is necessary for the ordered test to have clinical value). The NCCI Policy Manual states "[t]his type of testing is a category of reflex testing that must be distinguished from other reflex testing performed on a positive test result which may have clinical value without additional testing. . . . A laboratory should not routinely perform [such a test] unless

ordered by the treating physician." CMS, NCCI Policy Manual for Medicare Services X-3 (version 13.3).

56. At minimum, claims for laboratory testing must result from an order of the treating physician unless at least one of Medicare's specific limited exceptions is satisfied (*see supra* paragraphs 44-46).

57. Whatever the circumstances of the order, claims for secondary tests may only be made if the tests performed were medically necessary for that beneficiary, as evidenced by the fact that the results were communicated to and used by the treating physician in the beneficiary's medical care. Indeed, each claim form contains a separate affirmative certification of the medical necessity of the service rendered.

58. Defendant did not comply with these conditions of payment. Instead, Defendant engaged in a scheme to reflex add-on tests without the physician's consent, which were not necessary to the clinical value of the ordered test and which were not determined to medically-appropriate by the treating physician.

3. Compliance with the Anti-Kickback and Stark laws is a condition of payment under federally-funded healthcare programs.

59. The Anti-kickback Statute, 42 U.S.C. § 1320a-7b(b), arose out of congressional concern that payoffs to those who can influence healthcare decisions will result in goods and services being provided that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect the integrity of the program from these difficult to detect harms, Congress enacted a per se prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback gave rise to overutilization or poor quality of care. First enacted in 1972, Congress strengthened the statute in 1977 and 1987 to ensure that kickbacks

masquerading as legitimate transactions did not evade its reach. *See* Social Security Amendments of 1972, Pub. L. No. 92-603, §§ 242(b) and (c); 42 U.S.C. § 1320a-7b, Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93.

60. The Anti-kickback Statute prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending or arranging for federally-funded medical services, including services provided under the Medicare, Medicaid and (as of January 1, 1997) TRICARE programs. In pertinent part, the statute states:

> (b) Illegal remuneration
>
> (1) whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—
>
> (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.
>
> (2) whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—
>
> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

> (B) to purchase, lease, order or arrange for or recommend purchasing, leasing or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b(b). Violation of the statute can also subject the perpetrator to exclusion from participation in federal health care programs and, effective August 6, 1997, civil monetary penalties of $50,000 per violation and three times the amount of remuneration paid. 42 U.S.C. § 1320a-7(b)(7) and 42 U.S.C. § 1320a-7a(a)(7).

61. Regulations implementing the Anti-Kickback Act have created certain safe harbors protecting payments that meet narrow conditions. *See* 42 U.S.C. §1001.952. However, there is no safe harbor that applies to Bostwick's practice of offering illegal incentives to physician practices in exchange for laboratory referrals. Bostwick's solicitations and offers to physician practices all involve below fair market value remuneration which were intended to induce referrals of federally-funded business, and were in no way commensurate with an arm's length transaction.

62. Payment of remuneration of any kind violates the statute if one or any purpose for that remuneration was to induce referrals. Moreover, payments to physicians in return for the physicians' promises to refer patient services—including laboratory services—to a particular facility qualify as kickbacks. Giving a person the opportunity to earn money may also constitute an inducement under the Anti-Kickback statute.

63. Enacted as amendments to the Social Security Act, 42 U.S.C. § 1395nn (commonly known as the "Stark Statute") prohibits an entity providing healthcare items

or services from submitting Medicare claims for payment based on patient referrals from physicians having a "financial relationship" (as defined in the statute) with the hospital. The regulations implementing 42 U.S.C. § 1395nn expressly require that any entity collecting payment for a healthcare service "performed under a prohibited referral must refund all collected amounts on a timely basis." 42 C.F.R. § 411.353.

64. A financial relationship under the Stark laws specifically includes a relationship where the physician has a direct or indirect ownership or investment interest in an entity, or where the physician has a direct or indirect compensation relationship with an entity. 42 U.S.C. § 1395nn(a)(2)(A); 42 C.F.R. § 411.354 (a)(1). A compensation relationship under the Stark laws includes any arrangement whereby a physician receives remuneration, directly or indirectly, from an entity. 42 C.F.R. § 411.353(c). Illegal incentives offered by Bostwick create a compensation relationship under the Stark laws.

65. Congress enacted the Stark Statute in two parts, commonly known as Stark I and Stark II. Enacted in 1989, Stark I applied to referrals of Medicare patients for clinical laboratory services made on or after January 1, 1992 by physicians with a prohibited financial relationship with the clinical lab provider. Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, § 6204.

66. In 1993, Congress extended the Stark Statute (Stark II) to referrals for ten additional designated health services (DHS) effective January 1, 1995, including (1) inpatient and outpatient hospital services; (2) physical therapy; (3) occupational therapy; (4) radiology; (5) radiation therapy (services and supplies); (6) durable medical equipment and supplies; (7) parenteral and enteral nutrients, equipment, and supplies;

(8) prosthetics, orthotics, and prosthetic devices and supplies; (9) outpatient prescription drugs; and (10) home health services. 42 U.S.C. § 1395nn(h)(6).

67. Both the professional and technical components of the laboratory services which are the subject of this complaint are a designated health service (DHS) under Stark laws.

68. The Stark statute provides:

> (a) Prohibition of certain referrals
>
> (1) In general
>
> Except as provided in subsection (b) of this section, if a physician (or an immediate family member of such physician) has a financial relationship with an entity specified in paragraph (2), then --
>
> (A) the physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made under this subchapter, and
>
> (B) the entity may not present or cause to be presented a claim under this subchapter or bill to any individual, third party payor, or other entity for designated health services furnished pursuant to a referral prohibited under subparagraph (A).
>
> 42 U.S.C. § 1395nn (emphasis added).

69. The Stark laws expressly prohibits any entity from presenting or causing the presenting of any claim resulting from a referral from a physician who has a financial relationship with the entity, including the improper compensation relationships described herein, unless that relationship fits into one of the specific exceptions in the statute. *See, e.g.*, 42 C.F.R. § 411.357.

70. Bostwick's below-fair market value incentives offered in exchange for laboratory referrals do not fit within any exception. As such, Bostwick's compensation

relationships with physician practices prohibit him from submitting any claim to federal healthcare programs for referred laboratory specimens from those practices.

71. Compliance with both the Anti-kickback Act and the Stark laws is a condition of payment from federally-funded healthcare programs.

72. Every Medicare and Medicaid provider or supplier is required to sign a Provider Agreement certifying its understanding of the conditions of payment and its agreement to comply with the laws. The Provider/Supplier Agreement contains the following certification:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to [this provider/supplier/physician]. The Medicare laws, regulations, and program instructions are available through the [Medicare contractor].
>
> I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the provider's compliance with all applicable conditions of participation in Medicare.

73. Bostwick knowingly submitted, or caused to be submitted, false claims in violation of the Anti-Kickback and Stark laws by offering remuneration to physicians and their practices in exchange for increased laboratory referrals.

II. Defendant's Scheme to Falsely Bill Federal Programs.

A. False Billing for FISH Tests Performed Without a Physician's Order.

74. Bostwick Laboratories is engaging in a scheme to reflex FISH testing on positive or atypical urine cytologies without the consent of the treating physician.

75. Bostwick's Requisition Form gives no indication that the laboratory's policy is to reflex a FISH test after positive or atypical urine cytology.

76. Rather, Bostwick's Requisition Form has a pre-printed list of choices which includes (1) "Cytology"; (2) "Cytology/FISH;" and (3) Cytology/reflex FISH with a footnote on this choice that it "will reflex when results are atypical." The Requisition Form also allows FISH testing to be ordered separately. Further, the Form states in small print "Pathologist may order stains at an additional charge when required." (Form attached).

77. However, Bostwick Laboratories is billing for FISH tests performed upon an atypical result from urine cytology when the urologist has specifically ordered only a urine cytology on Bostwick's pre-printed requisition form.

78. An example of this scheme is as follows: On February 23, 2006, a urologist with RTR Urology practice in Venice, Florida ordered a cytology from Bostwick Labs for patient JZ (name withheld).[2]

79. Bostwick Labs did not seek the consent or order of the treating physician to perform an additional test.

80. In July 2007, RTR Urology was contacted by the patient, a Medicare beneficiary, who was outraged by the bill he received for the co-pay for an expensive test he did not realize had been ordered.

81. RTR Urology did not order the test and, upon inquiry, discovered that a FISH test had been performed under CPT code 88367.

82. RTR Urology Practice Administrator, Alexis Blakely, contacted a Bostwick representative and was told that it was Bostwick Laboratories' "policy" to reflex or perform FISH testing at the discretion of the pathologist on any atypical cytology.

[2] Patient names will be withheld and can be provided to the Court and counsel upon entry of a qualified protective order pursuant to the Health Insurance Portability and Accountability Act.

83. When the urology practice administrator responded that she had been advised that an order was required to perform such testing, the Bostwick manager told Ms. Blakely that she would have Bostwick's legal department address the issue and get back to her.

84. Ms. Blakely was contacted on July 18, 2007 by Ms. Raquel Corley, Contracts and Legal Administrator from Bostwick's Legal Department. Ms. Corley asked Ms. Blakely to send proof that Medicare required an order from the referring physician at RTR for the laboratory to perform an add-on FISH test based on cytology results. Ms. Blakely, in turn, requested that Bostwick provide a list of all patients of RTR urologists for whom Bostwick had performed FISH tests.

85. The RTR urologists include Dr. Robert R. Ross, Jr., Dr. Joseph J. Thro, Dr. Thomas J. Ruane, and Dr. Scott J. Rhamy.

86. On July 31, 2007, Ms. Blakely followed up with Ms. Corley to again request the list of RTR patients for which FISH was ordered. Ms. Corley responded that she was still working with the IT Department to extract the information. She also questioned Ms. Blakely: "Have you been able to locate that information regarding the alleged illegality of the physician's (pathologists) ordering additional tests for patients?"

87. Ms. Blakely was never provided the list of patients from Bostwick. Rather, on September 12, 2007, Ms. Corley sent the following electronic communication to Ms. Blakely:

> I do apologize for the delay in my response to you. I am actually in the process of transitioning out of one department to another within the company. Although your issue and the patients [sic] issue was a significant issue, it ended up getting jumbled in the midst of my transition. I did in fact receive some bits and pieces of information from my IT department. The information turned out not to be as helpful as I had

hoped it would be. Some of the pertinent details were unable to be captured as needed.

However, given the fact that the majority of your concern was directly connected with the performance of the FISH test and the financial burden that it presented to the patient, I attempted to have this specific charge cancelled by our outside billing agency. In the midst of making my request for this patient, it was brought to my attention that Mr. [JZ]'s[3] bill had already been paid since April of 2007 by Medicare and subsequently his private insurance. It turns out that Mr. [Z] only ended up paying $39.17 out of pocket for the service on May 21, 2007. Please keep in mind that this that Mr. [Z]'s FISH test did in fact render a positive result which will play, if it has not already, a significant part in his overall care.

At this time, I'd like to draw your attention to the original Bostwick Laboratories requisition form that was completed and sent in with Mr. [Z]'s specimen. This requisition clearly states that our pathologist may order stains at an additional charge when required (a copy of which has been attached for reference).

I have also attached for your record and review a copy of a CAP article which discusses the validity of the FISH stain and why it is so widely utilized and accepted by pathologists and laboratories within our industry.

Lastly, I am actually still waiting to receive some additional information from you. You previously stated to me that you knew for a fact that it was impermissible according to CAP's regulation and/or unlawful for any physician to order a test for a patient that the patient themselves and/or their primary physician did not personally authorize. Please confirm if you were ever able to locate this information. If so, please forward a copy to so that I may review it and retain it for my record?

Again, I do apologize for the delay in response and I do hope the above information will be helpful to you and Mr. [Z]. I just want to reiterate that Bostwick's process for performing the FISH test follows common industry standards and will continue to be utilized as deemed appropriate to ensure the best possible care for our patients.

88. Bostwick's legal department proffered explanation for performing and billing Medicare for an additional test without the physician's order was that the

[3] See *supra* note 2.

laboratory believed that it was authorized to perform the additional tests pursuant to the small print on their pre-printed form that "pathologist may perform additional stains at an additional charge when required."

89. Given that stains have their own separate CPT codes and that FISH tests are already listed separately on the pre-printed form, this proffered explanation has little merit. More to the point, it is blatantly non-compliant with conditions of payment for federally-funded healthcare programs.

90. Notwithstanding Medicare rules and regulations, Bostwick told RTR that it was its policy, and within its discretion, to perform and bill for FISH tests without the treating physician's order. Bostwick's admitted practice results in the submission of nonallowable claims to federally-funded healthcare programs.

91. On September 21, 2007, Ms. Blakely received an email from Richard T. Bostwick, legal counsel for Bostwick Laboratories, informing her: "I am the new in-house counsel with Bostwick Laboratories, Inc. and all further questions are to be directed to my attention."

92. By way of further demonstration of Bostwick's admitted policy of reflexing FISH tests with the treating physician's order, there were similar interactions in approximately August and September 2006 with North Fulton Urology, a large practice with offices in Roswell and Cumming, Georgia. A nurse at North Fulton contacted a manager at Relator's offices (who was also a former colleague from North Fulton) regarding his observations that Bostwick Laboratory was automatically reflexing the FISH test notwithstanding the fact that the North Fulton Urologists had not ordered the cytology with a reflex to FISH. She related that after North Fulton practice complained

to Bostwick about this conduct, Bostwick personnel began calling North Fulton urologists individually after cytology was ordered to attempt to persuade them to authorize a FISH test.

93. Upon information and belief, it is Bostwick's practice to have its personnel call urologists to persuade them to order expensive secondary tests if there is a question about their reflex practices.

94. Bostwick Laboratories is engaging in a scheme to perform and bill federally-funded and other health care programs for an expensive FISH test that have not been ordered or otherwise authorized by the treating physician.

95. Upon information and belief, this scheme is taking place at all its facilities and is ongoing.

96. Bostwick facilities service practices from all over the United States.

97. By its own admission, Bostwick Laboratories is employing this scheme knowingly, as that term is defined in the False Claims Act, such that it is acting with actual knowledge, deliberate ignorance, or in reckless disregard of the truth or falsity of the information submitted in connection with claims to federal healthcare programs.

B. False Billing for Tests Performed as a Result of Illegal Referrals in Violation of the Stark and Anti-kickback Laws.

98. Bostwick also increases its laboratory billing by offering urology practices incentives to refer laboratory testing, including expensive FISH testing, to Bostwick.

99. One example of such incentives includes a program developed by Bostwick to split the technical and professional component of laboratory services with the physicians, with little to no additional effort by the physician other than to refer the testing to Bostwick.

100. Bostwick refers to this program as its "Tech 26" program. Under this program, Bostwick performs the test, including the professional interpretation, prepares all the paperwork, and then sends the physician a complete report with interpretation and result (i.e., completely finished but for the signature line), so that the referring physician can then have the opportunity to simply sign the report and collect an additional fee from federal health care programs.

101. As Bostwick's form, titled "Tech 26 and FISH," explains: "Basically, your clinic sends your FISH specimen to Bostwick Laboratories and we perform and bill for the technical component and then we send the report to your pathologist to sign off on and you bill for the professional component." The form goes on to state: "There is no need to purchase a microscope, or anything else for that matter. The report includes a fluorescent photomicrograph of the FISH results and the initial diagnosis from our machine and cytotechs. There are no slides to store and you are able to bill Medicare."

102. Upon information and belief, Bostwick routinely has made such offers to providers in an effort to increase utilization of FISH and other diagnostic testing.

103. Upon information and belief, numerous relationships pursuant to Bostwick's Tech26 Programs have been and are currently operating, all which produce false claims due to the unlawful nature of the relationships.

104. Upon information and belief, Bostwick also offers other illegal incentives in exchange from referrals from physician-urologists. Indeed, a recent marketing flyer offers "custom business models" and "unique opportunities" to practices, including the "TC/PC" (technical/professional component split), "lab management," and "EMR Donation Program."

105. Yet another program by Bostwick goes beyond the "Tech26" offer and seeks to assist practices in setting up in-house laboratories, by offering below market value services to facilitate the set-up and operation of those laboratories and to secure referral of laboratory services not performed in-house, such as FISH testing.

106. These illegal incentives and resulting financial relationships with referring physicians are in violation of the Stark and Anti-Kickback laws. Claims resulting from illegally-referred patient specimens are false, whether billed by the practice or by Bostwick. By knowingly engaging in schemes in violation of the Anti-kickback and Stark laws, Bostwick submits, or causes the submission of, false claims to federal health care programs.

107. Upon information and belief, this scheme is on-going and is taking place nationally with practices that form Bostwick's customer base.

108. By its own admission, Bostwick Laboratories is employing this scheme knowingly, as that term is defined in the False Claims Act, such that it is acting with actual knowledge, deliberate ignorance, or in reckless disregard of the truth or falsity of the information submitted in connection with claims to federal healthcare programs.

COUNT I: FALSE CLAIMS ACT VIOLATIONS

109. Relator hereby incorporates and re-alleges paragraphs 1 through 108 as if fully set forth herein.

110. Defendant, by and through its agents, officers, and employees, knowingly presented or caused to be presented to officers or employees of the United States false claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1).

111. Defendant, by and through its agents, officers, and employees, also knowingly made, used, or caused to be made or used, false records or statements to

get false claims paid or approved by the Government, in violation of 31 U.S.C. § 3729(a)(2). These false records and statements included false and misleading requisition forms which did not disclose to the treating physician that the laboratory intended to perform and bill for additional or "reflexed" tests if the ordered test produced a positive or atypical result.

112. Defendant also knowingly presented or caused to be presented false or fraudulent claims for payment or approval to the United States for laboratory services provided pursuant to illegal referral arrangements as described herein, in violation of 42 U.S.C. § 1395nn(a) and 42 U.S.C. § 1320a-7b(b). These illegal referral arrangements included various incentives provided by Defendant in exchange for the submission to Defendant of specimens for diagnostic testing.

113. In engaging in the conduct alleged above, Defendant acted "knowingly" as that term is defined in 31 U.S.C. § 3729, in that it acted in deliberate ignorance or in reckless disregard of the truth or falsity of the information submitted in connection with the claims.

114. As a result of Defendant's violations of 31 U.S.C. § 3729, the United States has suffered damages in an amount to be determined at trial.

COUNT II: TEXAS FALSE CLAIMS ACT VIOLATIONS

115. The allegations in ¶¶ 1-114 are incorporated as if rewritten.

116. Defendant, by and through its agents, officers, and employees, presented or caused to be presented to the Texas Health and Human Services Commission claims that contained statements or representations that the defendant knew or should

have known to be false, in violation of the Texas False Claims Act, Tex. Hum. Res. Code Ann. § 32.039(b)(1).

117. The Texas Health and Human Services Commission is a "department" as that term is defined in Tex. Hum. Res. Code Ann. § 32.003(3).

118. Defendant, by and through its agents, officers, and employees, knowingly offered to pay, directly or indirectly, overtly or covertly remuneration in kind to another for securing patronage from persons licensed, certified, or registered by state health care regulatory agencies, in violation of Tex. Occ. Code Ann. § 102.001(a) as incorporated in the Texas False Claims Act, Tex. Hum. Res. Code Ann. § 32.039(b)(1-a).

119. Defendant, by and through its agents, officers, and employees, offered to pay, directly or indirectly, overtly or covertly remuneration in kind to another to induce persons to order services for which payment may be made, in whole or in part, under the medical assistance program, in violation of the Texas False Claims Act, Tex. Hum. Res. Code Ann. § 32.039(b)(1-e).

120. With respect to the falsity of the claims alleged herein, Defendant either "knew" or "should have known" as defined in Tex. Hum. Res. Code Ann. § 32.039(a)(4), in that it acted in deliberate ignorance or in reckless disregard of the truth or falsity of the information submitted in connection with the claims.

121. Such submissions, as alleged above, include false submissions related to illegal kickback schemes in violation of 42 U.S.C. § 1395nn(a) and 42 U.S.C. § 1320a-7b(b).

122. As a result of Defendant's violations of the Texas False Claims Act, Tex. Hum. Res. Code Ann § 32.039(b)(1), (1-a), and (1-e), the Texas Health and Human Services Commission has suffered damages in an amount to be determined at trial.

COUNT III: GEORGIA STATE FALSE MEDICAID CLAIMS ACT VIOLATIONS

123. The allegations in ¶¶ 1-114 are incorporated as if rewritten.

124. Defendant, by and through its agents, officers, and employees, knowingly presented or caused to be presented to officers or employees of the Georgia Medicaid Program false claims for payment or approval in violation of the Georgia State False Medicaid Claims Act, Ga. Code Ann. § 49-4-168.1(a)(1).

125. Defendant, by and through its agents, officers, and employees, also knowingly made, used, or caused to be made or used, false records or statements to get false claims paid or approved by the Georgia Medicaid Program in violation of the Georgia State False Medicaid Claims Act, Ga. Code Ann. § 49-4-168.1(a)(2). These false records and statements included false and misleading requisition forms which did not disclose to the treating physician that the laboratory intended to perform and bill for additional or "reflexed" tests if the ordered test produced a positive or atypical result.

126. In engaging in the conduct alleged above, Defendant acted "knowingly" as that term is defined in Ga. Code Ann. § 49-4-168(2)(B) and (C), in that it acted in deliberate ignorance or in reckless disregard of the truth or falsity of the information submitted in connection with the claims.

127. Such submissions, as alleged above, include false submissions related to illegal kickback schemes in violation of 42 U.S.C. § 1395nn(a) and 42 U.S.C. § 1320a-7b(b).

128. Defendant submitted false claims for reimbursement to the Georgia Medicaid Program as a consequence of entering into overt agreements for the referral of federally-funded healthcare business in exchange for various incentives, in violation of the Georgia State False Medicaid Claims Act, Ga. Code Ann. § 49-4-168.1(a)(1).

129. As a result of Defendant's violations of the Georgia State False Medicaid Claims Act, Ga. Code Ann. § 49-4-168.1(a)(1) and (a)(2), the Georgia Medicaid Program has suffered damages in an amount to be determined at trial.

COUNT IV: FLORIDA FALSE CLAIMS ACT VIOLATIONS

130. The allegations in ¶¶ 1-114 are incorporated as if rewritten.

131. Defendant, by and through its agents, officers, and employees, knowingly presented or caused to be presented to officers or employees of the Florida Agency for Health Care Administration, false claims for payment or approval in violation of the Florida False Claims Act, Fla. Stat. § 68.082(2)(a).

132. Defendant, by and through its agents, officers, and employees, also knowingly made, used, or caused to be made or used, false records or statements to get false claims paid or approved by the Florida Agency for Health Care Administration, in violation of the Florida False Claims Act, Fla. Stat. § 68.082(2)(b). These false records and statements included false and misleading requisition forms which did not disclose to the treating physician that the laboratory intended to perform and bill for additional or "reflexed" tests if the ordered test produced a positive or atypical result.

133. The Florida Agency for Health Care Administration is an "agency" as that term is defined in Fla. Stat. § 68.082(1)(a).

134. In engaging in the conduct alleged above, Defendant acted "knowingly" as that term is defined in Fla. Stat. § 68.082(1)(c)(2) and (3), in that it acted in deliberate ignorance or in reckless disregard of the truth or falsity of the information submitted in connection with the claims.

135. Such submissions, as alleged above, include false submissions related to illegal kickback schemes in violation of 42 U.S.C. § 1395nn(a) and 42 U.S.C. § 1320a-7b(b).

136. Defendant submitted false claims for reimbursement to the Florida Agency for Health Care Administration as a consequence of entering into overt agreements for the referral of federally-funded healthcare business in exchange for various incentives, in violation of the Florida False Claims Act, Fla. Stat. § 68.082(2)(a).

137. As a result of Defendant's violations of the Florida False Claims Act, Fla. Stat. § 68.082(2)(a) and (b), the Florida Agency for Health Care Administration has suffered damages in an amount to be determined at trial.

COUNT V: VIRGINIA FRAUD AGAINST TAXPAYERS ACT VIOLATIONS

138. The allegations in ¶¶ 1-114 are incorporated as if rewritten.

139. Defendant, by and through its agents, officers, and employees, knowingly presented or caused to be presented to officers or employees of the Commonwealth of Virginia, specifically of the Department of Medical Assistance Services, false claims for payment or approval in violation of the Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.3(A)(1).

140. Defendant, by and through its agents, officers, and employees, also knowingly made, used, or caused to be made or used, false records or statements to

get false claims paid or approved by the Commonwealth of Virginia, specifically, the Department of Medical Assistance Services, in violation of the Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.3(A)(2). These false records and statements included false and misleading requisition forms which did not disclose to the treating physician that the laboratory intended to perform and bill for additional or "reflexed" tests if the ordered test produced a positive or atypical result.

141. The Virginia Department of Medical Assistance Services falls with the definition of the term Commonwealth as defined in Va. Code Ann. § 8.01-216.2.

142. In engaging in the conduct alleged above, Defendant acted "knowingly" as that term is defined in Va. Code Ann. § 8.01-216.3(C)(ii) and (iii), in that it acted in deliberate ignorance or in reckless disregard of the truth or falsity of the information submitted in connection with the claims.

143. Such submissions, as alleged above, include false submissions related to illegal kickback schemes in violation of 42 U.S.C. § 1395nn(a) and 42 U.S.C. § 1320a-7b(b).

144. Defendant submitted false claims for reimbursement to the Virginia Department of Medical Assistance Services as a consequence of entering into overt agreements for the referral of federally-funded healthcare business in exchange for various incentives, in violation of the Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.3(A)(1).

145. As a result of Defendant's violations of the Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.3(A)(1) and (2), the Virginia Department of

Medical Assistance Services has suffered damages in an amount to be determined at trial.

COUNT VI: TENNESSEE MEDICAID FALSE CLAIMS ACT VIOLATIONS

146. The allegations in ¶¶ 1-114 are incorporated as if rewritten.

147. Defendant, by and through its agents, officers, and employees, presented or caused to be presented to the State of Tennessee claims known by the Defendant to be false for payment under the Medicaid program in violation of the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-182(a)(1)(A).

148. Defendant, by and through its agents, officers, and employees, also made, used, or caused to be made or used, records or statements known by the Defendant to be false to get false claims under the Medicaid program paid or approved by the State of Tennessee in violation of the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-182(a)(1)(B). These false records and statements included false and misleading requisition forms which did not disclose to the treating physician that the laboratory intended to perform and bill for additional or "reflexed" tests if the ordered test produced a positive or atypical result.

149. In engaging in the conduct alleged above, Defendant acted with "knowledge" as to the falsity of the claims, records, and statements as that term is defined in Tenn. Code Ann. § 71-5-182(b)(2) and (3), in that it acted in deliberate ignorance or in reckless disregard of the truth or falsity of the claims, records, and statements.

150. Such submissions, as alleged above, include false submissions related to illegal kickback schemes in violation of 42 U.S.C. § 1395nn(a) and 42 U.S.C. § 1320a-7b(b).

151. Defendant submitted false claims for reimbursement to the State of Tennessee as a consequence of entering into overt agreements for the referral of federally-funded healthcare business in exchange for various incentives, in violation of the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-182(a)(1)(A).

152. As a result of Defendant's violations of the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-182(a)(1)(A) and (B), the State of Tennessee has suffered damages in an amount to be determined at trial.

COUNT VII: NEW YORK FALSE CLAIMS ACT VIOLATIONS

153. The allegations in ¶¶ 1-114 are incorporated as if rewritten.

154. Defendant, by and through its agents, officers, and employees, knowingly presented or caused to be presented to employees, officers, or agents of the State of New York, specifically, the Department of Health, false claims for payment or approval in violation of the New York False Claims Act, N.Y. State Fin. Law § 189(1)(a).

155. Defendant, by and through its agents, officers, and employees, also knowingly made, used, or caused to be made or used, false records or statements to get false claims paid or approved by the State of New York, specifically, the Department of Health, in violation of the New York False Claims Act, N.Y. State Fin. Law § 189(1)(b). These false records and statements included false and misleading requisition forms which did not disclose to the treating physician that the laboratory

intended to perform and bill for additional or "reflexed" tests if the ordered test produced a positive or atypical result.

156. The New York Department of Health falls with the definition of the term "state" as defined in N.Y. State Fin. Law § 188(7).

157. In engaging in the conduct alleged above, Defendant acted "knowingly" as that term is defined in N.Y. State Fin. Law § 188(3)(b) and (c), in that it acted in deliberate ignorance or in reckless disregard of the truth or falsity of the information submitted in connection with the claims.

158. Such submissions, as alleged above, include false submissions related to illegal kickback schemes in violation of 42 U.S.C. § 1395nn(a) and 42 U.S.C. § 1320a-7b(b).

159. Defendant submitted false claims for reimbursement to the New York Department of Health as a consequence of entering into overt agreements for the referral of federally-funded healthcare business in exchange for various incentives, in violation of the New York False Claims Act, N.Y. State Fin. Law § 189(1)(a).

160. As a result of Defendant's violations of the New York False Claims Act, N.Y. State Fin. Law § 189(1)(a) and (b), the New York Department of Health has suffered damages in an amount to be determined at trial.

COUNT VIII: DISTRICT OF COLUMBIA FALSE CLAIMS ACT VIOLATIONS

161. The allegations in ¶¶ 1-114 are incorporated as if rewritten.

162. Defendant, by and through its agents, officers, and employees, knowingly presented or caused to be presented to employees, officers, or agents of the District of Columbia, specifically, the Medical Assistance Administration, false claims for payment

or approval in violation of the District of Columbia False Claims Act, D.C. Code § 2-308.14(a)(1).

163. Defendant, by and through its agents, officers, and employees, also knowingly made, used, or caused to be made or used, false records or statements to get false claims paid or approved by the District of Columbia, specifically, the Medical Assistance Administration, in violation of the District of Columbia False Claims Act, D.C. Code § 2-308.14(a)(2). These false records and statements included false and misleading requisition forms which did not disclose to the treating physician that the laboratory intended to perform and bill for additional or "reflexed" tests if the ordered test produced a positive or atypical result.

164. In engaging in the conduct alleged above, Defendant acted "knowingly" as that term is defined in D.C. Code § 2-308.13(3)(A)(ii) and (iii), in that it acted in deliberate ignorance or in reckless disregard of the truth or falsity of the information submitted in connection with the claims.

165. Such submissions, as alleged above, include false submissions related to illegal kickback schemes in violation of 42 U.S.C. § 1395nn(a) and 42 U.S.C. § 1320a-7b(b).

166. Defendant submitted false claims for reimbursement to the District of Columbia Medical Assistance Administration as a consequence of entering into overt agreements for the referral of federally-funded healthcare business in exchange for various incentives, in violation of the District of Columbia False Claims Act, D.C. Code § 2-308.14(a)(1).

167. As a result of Defendant's violations of the District of Columbia False Claims Act, D.C. Code § 2-308.14(a)(1) and (2), the District of Columbia Medical Assistance Administration has suffered damages in an amount to be determined at trial.

COUNT IX: INDIANA FALSE CLAIMS ACT VIOLATIONS

168. The allegations in ¶¶ 1-114 are incorporated as if rewritten.

169. Defendant, by and through its agents, officers, and employees, knowingly or intentionally presented to the State of Indiana false claims for payment or approval in violation of the Indiana False Claims Act, Ind. Code § 5-11-5.5-2(b)(1).

170. Defendant, by and through its agents, officers, and employees, also knowingly or intentionally made or used false records or statements to obtain payment or approval of false claims by the State of Indiana in violation of the Indiana False Claims Act, Ind. Code § 5-11-5.5-2(b)(2). These false records and statements included false and misleading requisition forms which did not disclose to the treating physician that the laboratory intended to perform and bill for additional or "reflexed" tests if the ordered test produced a positive or atypical result.

171. In engaging in the conduct alleged above, Defendant acted "knowingly" as that term is defined in Ind. Code § 5-11-5.5-1(4)(B) and (C), in that it acted in deliberate ignorance or in reckless disregard of the truth or falsity of the information submitted in connection with the claims.

172. Such submissions, as alleged above, include false submissions related to illegal kickback schemes in violation of 42 U.S.C. § 1395nn(a) and 42 U.S.C. § 1320a-7b(b).

173. Defendant submitted false claims for reimbursement to the State of Indiana as a consequence of entering into overt agreements for the referral of federally-funded healthcare business in exchange for various incentives, in violation of the Indiana False Claims Act, Ind. Code § 5-11-5.5-2(b)(1).

174. As a result of Defendant's violations of the Indiana False Claims Act, Ind. Code § 5-11-5.5-2(b)(1) and (2), the State of Indiana has suffered damages in an amount to be determined at trial.

PRAYER FOR RELIEF

WHEREFORE, Relator, on behalf of himself and the United States, demands judgment against Defendants, as follows:

AS TO COUNT I,

1. That this Court enter judgment against the Defendant in an amount equal to three times the amount of damages the United States government has sustained because of Defendant's actions, plus a civil penalty of $11,000.00 for each false claim, together with the costs of this action, with interest, including the cost to the United States Government for its expenses related to this action;

2. That Relator be awarded all costs incurred, including his attorneys' fees;

3. That in the event the United States Government intervenes in this action, Relator be awarded twenty-five percent (25%) of any proceeds of the claim, and that in the event the United States Government does not intervene in this action, Relator be awarded thirty percent (30%) of any proceeds;

4. That the United States and Relator receive all relief, both in law and in equity, to which she is entitled.

AS TO COUNTS II THROUGH IX,

5. That the Court enter judgment against the Defendant in the maximum amount of damages available under each state, commonwealth, or district False Claims Act over which the Court accepts jurisdiction, to include any multipliers provided in such Acts;

6. That the Court enter judgment against the Defendant for the maximum amount of civil penalties in favor of those states, commonwealths, or districts whose False Claims Acts provide for such relief, together with such state's, commonwealth's, or district's costs of this action;

7. That Relator be awarded, under each state, commonwealth, or district False Claims Act pursuant to which he sues, the maximum share permitted by law of all amounts recognized by such state or commonwealth as a consequence of this action;

8. That Relator be awarded all costs, attorneys' fees, and litigation expenses;

9. That each state, commonwealth, district, and Relator receive all relief, both at law and in equity, to which they may reasonably appear entitled.

Respectfully submitted,

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